

JUN 21 2006

**EXHIBIT 2**

**510(k) Summary**

Medical Devices/Padpro, Inc.

5643 Plymouth Rd.

Ann Arbor, MI 48105

Phone: 734-663-0132

Fax: 734 213 5640

Contact: Stuart Schulman, President

Prepared: May 23, 2006

K061606

1. Identification of the Device:  
Proprietary-Trade Name: Defibrillator Cable Tester Model DT2200  
Classification Name: Tester, Defibrillator  
Common/Usual Name: Defibrillator Test Load
2. Equivalent legally marketed device: This device identical in function and similar in design to the Physio-control Defibrillator Test Load, K790394.
3. Indications for Use: This device is designed to serve as a 50 ohm cable test load for low energy DC defibrillators.
4. Description: The device has a built-in load resistance of 50 ohms with a test lamp which briefly illuminates if defibrillator energy of greater than 200 joules is detected. The device has a connector which is compatible with the PadPro System disposable defibrillator pads (K003548, K014209, K020288, K020203, and K020743).
5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Physio-control Defibrillator Test Load, K790394	Defibrillator Cable Tester Model DT2200
Indications for use	This device is designed to serve as a 50 ohm cable test load for low energy DC defibrillators.	SAME
Where used	Hospitals and Paramedic situations	SAME
Basic features	Dummy load and green LED	SAME
Test load	50 ohms nominal, 50 watt	SAME
Construction	A printed circuit board mounted inside an ABS plastic enclosure with a green indicator LED	SAME
LED turn on threshold	Not specified, "Set defibrillator energy at 360 joules"	200 joules or more
Connector	Physio-control Post Connector	PadPro System: Anderson touch proof connector
Power Source	From defibrillator	SAME
Size	6.25" x 3.625" x 1.75"	5" x 2.5" x 2.125"
Enclosure	ABS Plastic, Beige	ABS Plastic, Gray

6. Conclusion In all material respects, the Defibrillator Cable Tester Model DT2200 is substantially equivalent to other test loads that are legally marketed for this purpose.

**EXHIBIT 3**

Page 7 of 33

page 1 of 1



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 21 2006

Medical Devices/Padpro Inc.  
c/o Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC.  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

Re: K061606  
Trade Name: Defibrillator Cable Tester Model DT2200  
Regulation Number: 21 CFR 870.5325  
Regulation Name: Defibrillator Tester  
Regulatory Class: II (two)  
Product Code: DRG  
Dated: June 6, 2006  
Received: June 9, 2006

Dear Mr. Job

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120 (see bottom for #s). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Defibrillator Cable Tester Model DT2200

Indications For Use: This device is designed to serve as a 50 ohm cable test load for low energy DC defibrillators.


Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K061606

Page 1 of 1